SUPPLEMENTARY INFORMATION
CERTIFICATE OF EXPORTABILITY REQUESTS

1. Requester information (name; firm; address; telephone number; FAX number; firm Tax ID code):

2. Manufacturer information (firm; address (P.O. Box not acceptable); registration number; date of last FDA inspection)

3. Product Name

4. List country(ies) for which the Certificates are requested.

5. Indicate what product information should appear on the certificate, if the country destination should be listed on the certificate, and the total number of certificates requested.

6. Indicate whether you are exporting pursuant to section 801(e) or section 802 of the Act.

NOTE: To meet the requirements for exporting products pursuant to section 802 of the Act, an exporter must maintain records of the product(s) exported and the countries to which they were exported. Notification of exporting unapproved drugs or devices, including biologics, pursuant to section 802(g) of the Act is separate from requesting or receiving a Certificate of Exportability. Notification to FDA is required when the exporter first begins to export and should be sent to the same address for requesting export certificates.

EXPORTER'S CERTIFICATION STATEMENT - "Certificate of Exportability"

Firm Name:

As the responsible official or designee of the company named above, I hereby certify to the United States Food and Drug Administration that:

- the product(s) accords to the specifications of the foreign purchaser;
- the product(s) are not in conflict with the laws of the country to which it is intended for export;
- the shipping package for the product(s) are labeled on the outside that it is intended for export; and
- the product(s) are not sold or offered for sale in the United States.

(Check below, if exporting under Section 802 of the Act.)

___In addition, I hereby certify to the FDA that pursuant to Section 802(f)(1) of the Act, the product(s) being exported have been manufactured, processed, packaged, and held in substantial conformity with current good manufacturing practice requirements.

_____

Signature Date

_____

Name and Title

Making or submitting false statements on any documents submitted to FDA may constitute violations of the United States Code Title 18, Chapter 47, Section 1001 with penalties including up to $250,000 in fines and up to 5 years imprisonment.